



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

WARNING LETTER
2000-DT-37

August 14, 2000

Mr. Philo C. Woo, President
Chung Wah Co.
7325 Sarena
Detroit, Michigan 48210

Dear Mr. Woo:

During the period of June 27 and July 5, 2000, the Food and Drug Administration (FDA) conducted an inspection of your facility located at 7325 Sarena, Detroit, Michigan. The inspection was conducted to determine compliance with The Federal Food, Drug and Cosmetic Act (hereafter referred to as "The Act") and to determine if your mung bean sprout processing operations were conducted under sanitary conditions.

During the inspection, the FDA investigator observed significant shortcomings in your operations that are not in compliance with The Act. The FDA investigator presented your firm with a list of inspectional observations (form FD-483) which presents the investigator's evaluation of your firm's performance with respect to compliance with The Act.

During the inspection, it was determined that your firm is not analyzing the spent irrigation water for your mung bean sprout operation.

As such, your sprout products are adulterated within the meaning of 402(a)(4) of The Act because they are being produced under insanitary conditions that may render sprouts injurious to health. The conditions under which these sprout products are being produced are considered unsanitary since effective preventive controls, particularly microbial testing of spent irrigation water, have not been adopted and implemented by your sprouting facility.

Your firm's sprouts are further adulterated within the meaning of 402(a)(4) of The Act because they have been prepared, packed or held under insanitary conditions whereby they may have been contaminated with filth or whereby they may have been rendered injurious to health. Examples of these conditions include:

- 1.) Bags of mung bean seeds were noted to be stored directly on the floor of your warehouse. In various locations throughout the warehouse, rodent pellets were observed directly on top of stored bags of seeds.
- 2.) Examination of bags of mung bean seeds in your warehouse facility revealed three bags to bear rodent urine stains on the outer surfaces of the bags.
- 3.) The floor area in the warehouse where bags of mung bean seeds are stored were observed to contain over 100 rodent droppings and an estimated 1,000 plus dead insects. Additionally, rat poison pellets were noted to be strewn on this floor directly next to bags of seeds.
- 4.) Live insects (which appeared to be roaches) were observed in the production area in several plastic drums of mung bean seeds. Dead insects (which appeared to be roaches) were also observed on the floor in the packaging room where finished sprout products in open laundry baskets or plastic bags are stored or processed.
- 5.) The ceilings of the growing rooms and walk in coolers were observed to be dripping condensate to the areas below. It was further noted that these rooms contained uncovered laundry baskets of finished sprouts below these ceilings.
- 6.) What appeared to be live worms were observed in cracks or crevices of the production room floor. It was also observed that buckets of mung bean seeds were stored directly on this same floor. Further, it was observed that some of these buckets are stacked on top of each other, exposing the bottom of some buckets to the opened buckets below.

- 7.) Containers of various pesticides and chemicals were observed stored haphazardly on the floor area of the seed storage warehouse, within 5 feet of stored bags of mung bean seeds which were also stored on the floor. These included products such as weed killer, [REDACTED] aerosol, [REDACTED] in a pump/spray container, [REDACTED] aerosol, and a plastic container of [REDACTED].

The above is not intended to be an all inclusive list of deviations at your facility. It is your responsibility to assure that your establishment is in full compliance with all requirements of the federal regulations.

We note that several of these observations, such as water condensation problems, what appeared to be worms in the cracks of the floor, etc., were also noted in previous inspections of your facility.

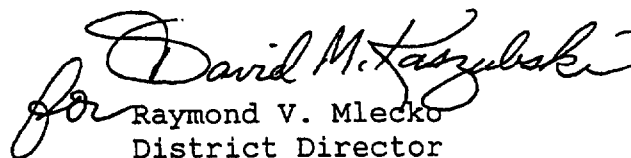
We note that you took corrective action on some of the deficiencies pointed out to you. However, all deficiencies need to be addressed.

You should take prompt measures to correct all deviations and take action to prevent their recurrence in the future. Failure to promptly correct the deviations noted may result in regulatory action without further notice. Such action includes seizure and or injunction.

Please notify this office in writing, within fifteen (15) working days of your receipt of this letter, of the specific steps you have taken to correct this violation, including an explanation of each step taken to prevent its recurrence. If corrections cannot be completed within 15 working days, please state the reason for the delay, and the time in which the corrections will be completed.

Your written reply should be directed to Mr. Dennis P. Degan, Compliance Officer, U.S. Food and Drug Administration, 1560 E. Jefferson Avenue, Detroit, MI 48207, telephone 313-226-626, extension 135.

Sincerely yours,


for Raymond V. Mlecko
District Director